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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,981	01/25/2001	Aladar A. Szalay	13070-1	5416

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SHELDON & MAK
Attn: David A. Farah, M.D.
225 South Lake Avenue, Suite 900
Pasadena, CA 90101

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,981	SZALAY ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed December 22, 2003 has been entered. The examiner acknowledges the drawings submitted on December 22, 2003. Claim 1 has been amended. Claims 13-22 have been cancelled. Claims 23-32 have been newly added.

Election/Restrictions

2. Newly submitted claims 23- 32 are directed to an invention that is independent or distinct from the invention originally claimed because even though the methods have the same preamble, the method described in claims 23-32 is patentably distinct. The methods are distinct as claimed because claims 23-32 have different method steps, with different functions and those effects result in different final outcomes. Claims 23-32 are drawn to a method for evaluating whether a material will allow bacteria to pass through, around or into the material using a distinctly different modified bacteria, i.e., a bacteria that comprises two separately detectable signals. Moreover, claims 23-32 are further drawn to an evaluation method wherein the method places the modified bacteria in the center of a hollowed out, extracted natural tooth where the root end of the tooth is sealed with the material, thus this method has a different function. The method of claims 23-32 does not produce the same results. The groups produce different effects and different functions when compared to the other group. Therefore, the inventions are unrelated.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 1-12 are under consideration in this office action.

Drawings

4. The drawings were received on December 22, 2003. These drawings are acceptable.

Response to Arguments

5. Applicant's arguments filed December 22, 2003 have been fully considered but they are not persuasive for the reasons discussed below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The rejection of claims 1-2, 4, 7 and 11 under 35 U.S.C. 102(b) as being anticipated by Loessner et al., is maintained for the reasons asserted in the previous office action. The rejection was on the grounds that Loessner et al., teach a method for evaluating whether a non-living material will allow modified living bacteria to pass through the material or around the material or into the material comprising providing living bacteria with a first detectable signal; placing the modified bacteria on the first side of the material and detecting whether the first signal is present on the material.

Applicants assert that the modified bacteria of Loessner et al., are mixed homogeneously throughout the sample to be tested and that the samples were not artificially contaminated with the modified living bacteria at specific areas. However this argument is not persuasive because the claims are drawn to a method which simply states that the placement of the modified bacteria are on the first side of the material. There is no limitation on whether there is artificial contamination. There is no limitation on whether or not the modified bacteria are mixed homogeneously throughout the sample being tested. The only limitation is that the bacteria are placed in the material; Loessner et al., teach placement on the material thereby meeting the limitations of the claims. Thus, applicants' arguments are not persuasive and the rejection is thereby maintained.

7. The rejection of claims 1-8 and 11 under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) in view of Contag et al., is maintained. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Miller et al., to detect bacterial contamination using living bacteria with incorporated functional luciferase which produce a detectable signal as taught by Contag et al.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). The references in combination teach that one would have a reasonable expectation of success because no more than routine skill would have been required to exchange the two step method for creating modified bacteria of Miller et al., in view of Contag et al., for the more convenient modified bacteria used to detect bacterial contamination at a site other than the initial inoculation site is well known in the art as capable of such detection.

Applicants assert that since the route of inoculation in Contag et al., was intraperitioneal injection it is not possible to say that the pathogen actually traversed a particular tissue rather than entered the tissue through vascular spread or some other mechanisms. However, it is the examiner's position that the issue is not the route of spread but whether the bacteria can the detected at a different or second site than where it was initially placed. Contag et al., clearly teach that detection of the bacteria can occur at a different site, and there is no need to identify the route of distribution since the claims are not drawn to limiting the route of distribution, rather the claims are drawn to detecting the bacteria signals. Thus, if the bacteria spread and are capable of being detected at a site other than the original site, the method steps of Miller et al., (US Patent 5,736,351) in view of Contag et al., meet the limitations of the claims.

Applicants urge that Contag et al., teach pathogen distribution in living material, i.e., tissue, and thereby does not teach the instant invention. However, applicants' arguments against the Contag et al., reference individually is not persuasive since one cannot show nonobviousness where the rejections are based on combination of the Miller et al., (US Patent 5,736,351) and Contag et al., references. Miller et al., teach a

method for detecting the presence and determining the quantity of contaminants present on a wide variety of surfaces of meat or other foodstuffs, equipment, materials in medical situations using bioluminescence or chemiluminscence (col. 1 lines 10-26). Miller et al., teach chemiluminescent detection by iosluminols and other similar visually detectable compounds (col. 2 lines 10-14). Thus, Miller et al., disclose using multiple and different bioluminescent labels. Microbial contamination is the significant cause of morbidity and mortality, therefore the rapid and routine quantitative determination of bacteria particularly those present on the surfaces of materials is of vital importance (col. 1 lines 27-31). The method procedures teach general bacterial screens on hard surfaces, and screen materials; thus the references teach a method for the evaluation of non-living material, contrary to applicants' assertions.

In response to applicant's argument that Contag et al., is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Contag et al., teach photonic detection of bacterial pathogens which is an analogous field of art. Moreover, Contag et al's photonic detection of bacterial pathogens is reasonably pertinent to the particular problem with which the applicant was concerned (evaluation and detection of the modified bacteria on the material), in order to be relied upon as a basis for rejection of the claimed invention. Thus Contag et al., is relevant and analogous art.

Applicants assert that Miller et al., do not disclose any methods for evaluating whether a material allows for the bacteria to pass through or around the material. In response to applicant's arguments, the recitation of a method for evaluating whether a material will allow modified living bacteria to pass through the material or around the material or into the material has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Miller et al., in view of Contag et al., teach methods for determining the presence and quantity of bacteria from a wide variety of non-living materials comprising the steps of providing the modified bacteria; placing the bacteria on the first side of the material; and detecting whether the signal is present on a second side of the material.

Therefore, no more than routine skill would have been required to make the modified bacteria that was already known in the art to be able to detect the bacteria since the bioluminescence method for evaluating whether a material is contaminated with bacteria is well known in the art and been found to be rapid, inexpensive and convenient as compared to other detection methods. Thus applicants' arguments are not persuasive.

8. The rejection of claims 9 and 12 under 35 U.S.C. 103(a) as being unpatentable over Miller et al., (US Patent 5,736,351) and Contag et al., and further in view of Holen (US Patent 5,814,331) is maintained. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants' invention to modify the methods taught by Miller et al., and Contag et al., to detect bacterial contamination on teeth as taught by Holen. Miller et al., and Contag et al., have been discussed above.

Applicants' assert that in view of the arguments drawn to Miller et al., and Contag et al, this rejection should be withdrawn. However, it is the examiner's position that the rejection should be maintained, contrary to applicants' assertion. In this case, one would have a reasonable expectation of success because no more than routine skill would have been required to exchange the materials of Miller et al., and Contag et al., for a tooth, since the art teaches that bacterial contamination of teeth can cause periodontal diseases. Moreover, no more than routine skill would have been required to exchange the material being tested because it was already known in the art to be able to detect the bacteria on tooth surfaces. Thus, applicants' assertions are not persuasive.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 16, 2004

L. R. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600